

Definitions and criteria for diabetic foot disease

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ABSTRACT

Several disciplines are involved in the management of diabetic foot disease and having a common vocabulary is essential for clear communication. Based on the systematic reviews of the literature that form the basis of the International Working Group on the Diabetic Foot (IWGDF) Guidelines, the IWGDF has developed a set of definitions and criteria for diabetic foot disease. This document describes these definitions and criteria. We suggest these definitions be used consistently in both clinical practice and research, to facilitate clear communication between professionals.

INTRODUCTION

Several disciplines are involved in the management of diabetic foot disease, and interdisciplinary treatment is the cornerstone of its management and prevention. With all these disciplines involved, having a common vocabulary is essential for clear communication. For research purposes, clear and unequivocal definitions are imperative for study methodology to be comparable between studies and repeatable in different settings.

Since its inception in 1999, the International Working Group on the Diabetic Foot (IWGDF) has created a set of core definitions related to diabetic foot disease, its diagnoses and interventions. These definitions were published online or as addendum to the systematic reviews (1). The Reporting Standards of studies and papers on the prevention and management of foot ulcers in diabetes (2) also notes that these definitions should be used, to facilitate uniform reporting.

We herein provide an update of all definitions and criteria for diabetic foot disease based on the systematic reviews of the literature that form the basis of the 2019 IWGDF Guidelines (3-9). Where possible, we have kept the definitions from previous versions, to facilitate consistent comparison with older studies. We have only made changes when the evidence required updates of older definitions. When no previous definition was available, we developed each based on the literature findings. New definitions have an asterisk (*), updated definitions an obelisk ([†]) to indicate the change.

We do not provide definitions on diabetes, nor on other (chronic) diseases, unless it is specifically relevant to the topic (e.g. for peripheral artery disease-related definitions). We suggest the definitions in this paper be used consistently in both clinical practice and research, to facilitate clear communication between professionals.

DIABETIC FOOT DISEASE RELATED DEFINITIONS

Diabetic foot: Infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of a person with (a history of) diabetes mellitus.

Diabetic neuropathy: The presence of symptoms or signs of nerve dysfunction in a person with (a history of) diabetes mellitus, after exclusion of other causes.

Loss of protective sensation: Inability to sense light pressure e.g. as applied with a 10 gram Semmes-Weinstein monofilament.

Neuro-osteoarthropathy (Charcot-foot): Non-infectious destruction of bone and joint(s) associated with neuropathy, which, in the acute phase, is associated with signs of inflammation.

FOOT-RELATED DEFINITIONS

Forefoot*: The anterior part of the foot, that is composed of the metatarsal bones, the phalanges and associated soft tissue structures.

Midfoot*: The part of the foot that is composed of the cuboid, navicular, and cuneiform bones, and associated soft tissue structures.

Rearfoot or hindfoot*: The posterior part of the foot that is composed of the talus and calcaneum, and associated soft tissue structures.

Plantar foot surface*: The underside or weight-bearing surface of the foot.

Non-plantar foot surface*: All other surfaces of the foot not defined as plantar.

Foot deformity: Structural abnormalities of the foot, such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, pes cavus, pes planus, and residuals of Charcot neuro-osteoarthropathy, trauma, amputations or other foot surgery.

Limited joint mobility: reduced mobility of the joints of the foot, including the ankle, caused by changes in joints and associated soft tissues.

Callus: Hyperkeratosis caused by excessive mechanical loading.

Plantar pressure*: The distribution of forces over a given plantar foot surface, mathematically defined as 'force divided over the contact area'. Often expressed as peak pressure or pressure-time integral.

FOOT ULCER RELATED DEFINITIONS

Foot ulcer[†]: A break of the skin of the foot that includes minimally the epidermis and part of the dermis.

Diabetic foot ulcer*: Foot ulcer in a person with diabetes mellitus.

Healed foot ulcer: Intact skin, meaning complete epithelialization without any drainage of a previously ulcerated site.

Foot in remission*: Intact skin, and absence of infection, of the complete foot after healing of any ulcer(s).

Pre-ulcerative lesion*: Foot lesion that has a high risk to develop into a foot ulcer, such as intra- or subcutaneous haemorrhage, blister, or skin fissure not penetrating into the dermis.

Foot lesion: Any abnormality associated with damage to the skin, nails or deep tissues of the foot.

First-ever foot ulcer[†]: An ulcer occurring in a patient who has never before had a foot ulcer.

Recurrent foot ulcer: New ulcer in a patient who has a history of ulceration, irrespective of location and time, since previous foot ulcer.

Superficial foot ulcer[†]: An ulcer not penetrating any structure deeper than the dermis.

Deep foot ulcer[†]: An ulcer penetrating below the dermis into subcutaneous structures, such as fascia, muscle, tendon or bone.

Ulcer-free survival days*: Days that a patient is alive and without a foot ulcer.

PERIPHERAL ARTERY DISEASE RELATED DEFINITIONS

Peripheral artery disease (PAD): Obstructive atherosclerotic vascular disease with clinical symptoms, signs or abnormalities on non-invasive vascular assessment, resulting in disturbed or impaired circulation in one or more extremities

Claudication: Pain in thigh or calf that occurs during walking and is relieved by rest, and is due to peripheral arterial disease.

Rest pain: Severe and persistent pain localized in the foot due to peripheral artery disease that can, at least partially, be relieved by putting the foot in a dependent position.

Angioplasty[†]: An endovascular technique used to re-establish the patency of an artery by percutaneous transluminal or subintimal procedures.

Neuro-ischemic foot ulcer[†]**:** An ulcer in the presence of both neuropathy and peripheral artery disease.

INFECTION RELATED DEFINITIONS

Infection: A pathological state caused by invasion and multiplication of microorganisms in host tissues accompanied by tissue destruction and/or a host inflammatory response.

Superficial infection: An infection of the skin not extending to any structure deeper than the dermis.

Deep infection: An infection that extends deeper than the dermis, that may include abscess, septic arthritis, osteomyelitis, septic tenosynovitis or necrotizing fasciitis.

Cellulitis⁺: An infection of the skin (epidermis or dermis) manifested by one or more of the following: induration, erythema, warmth, pain or tenderness.

Osteitis: Infection of the bone cortex without involvement of bone marrow.

Osteomyelitis: Infection of the bone, with involvement of the bone marrow.

Pathogen*: A microorganism that is considered to be causing an infection, as opposed to colonizing or contaminating a wound.

AMPUTATION RELATED DEFINITIONS

Amputation: Resection of a segment of a limb through a bone or through a joint.

Major amputation: Any resection proximal to the ankle.

Major amputation levels:

TF = transfemoral amputation (frequently referred to as 'above knee amputation') KD = knee disarticulation (frequently referred to as 'through knee amputation') TT = transtibial amputation (frequently referred to as 'below knee amputation') Minor amputation: Any resection through or distal to the ankle.

Minor amputation levels:

- 1. toe amputation
- 2. metatarsal-phalangeal disarticulation
- 3. distal transmetatarsal amputation
- 4. proximal transmetatarsal amputation
- 5. tarso-metatarsal disarticulation
- 6. midtarsal metatarsal disarticulation
- 7. ankle disarticulation

MISCELLANEOUS DEFINITIONS

Interdisciplinary (or multidisciplinary) clinical team*: A generally consistent grouping of people from relevant clinical disciplines, whose interactions are guided by specific team functions and processes to achieve team- and patient-defined favourable outcomes. (Based on: (10)).

Necrosis: Devitalized (dead) tissue.

Gangrene[†]: A condition that occurs when body tissue dies, due to insufficient blood supply, infection or injury. Without infection this generally results in dry and black tissue, frequently called dry gangrene; when the tissue is infected, with accompanying putrefaction and surround cellulitis, it is often called wet gangrene.

Oedema of the lower limb: Swelling of the leg or foot caused by increased interstitial fluid.

Erythema[†]: A pink or red discoloration that blanches to some degree on compression, caused by increased blood flow to the involved tissue.

Debridement[†]: Removal of callus or dead tissue that can be surgical ("sharp") or non-surgical (e.g. abrasion, chemical).

IWGDF SYSTEMS

Category	Ulcer risk	Characteristics	Frequency*
0	Very low	No LOPS and No PAD	Once a year
1	Low	LOPS or PAD	Once every 6-12 months
2	Moderate	LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity	Once every 3-6 months
3	High	LOPS or PAD, and one or more of the following: - history of a foot ulcer - a lower-extremity amputation (minor or major) - end-stage renal disease	Once every 1-3 months

IWGDF ulcer risk stratification system:

Note: LOPS = Loss of protective sensation; PAD = peripheral artery disease. *: Screening frequency is based on expert opinion, since no evidence is available to support these intervals. When the screening interval is close to a regular diabetes check-up, consider to screen the foot at that check-up.

IWGDF / IDSA foot infection classification system:

Clinical classification of infection, with definitions	IWGDF classification
Uninfected:	
No systemic or local symptoms or signs of infection	1 (uninfected)
Infected:	
At least two of these items are present:	
 Local swelling or induration 	
 Erythema >0.5 cm* around the wound 	
Local tenderness or pain	
Local increased warmth	
Purulent discharge	
And no other cause(s) of an inflammatory response of the skin (e.g. trauma,	
gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis or venous	
stasis)	
- Infection with no systemic manifestations (see below) involving	2 (mild infection)
 only the skin or subcutaneous tissue (not any deeper tissues), and 	
 any erythema present does not extend >2 cm** around the wound 	
 Infection with no systemic manifestations, and involving: 	3 (moderate infection)
 erythema extending ≥2 cm* from the wound margin, and/or 	
 tissue deeper than skin and subcutaneous tissues (e.g. tendon, muscle, 	
joint, bone,)	
- Any foot infection with associated systemic manifestations (of the systemic	4 (severe infection)
inflammatory response syndrome [SIRS]), as manifested by ≥ 2 of the	
following:	
• Temperature >38 °C or <36 °C	
• Heart rate >90 beats/minute	
 Respiratory rate >20 breaths/minute or PaCO₂ <4.3 kPa (32 mmHg) 	
• White blood cell count >12,000/mm ³ , or <4,000/mm ³ , or >10% immature	
(band) forms	
- Infection involving bone (osteomyelitis)	Add "(O)" after 3 or 4***

Note: *Infection refers to any part of the foot, not just of a wound or an ulcer. **In any direction, from the rim of the wound. The presence of clinically significant foot ischemia makes both diagnosis and treatment of infection considerably more difficult. ***If osteomyelitis is demonstrated in the absence of ≥2 signs/symptoms of local or systemic inflammation, classify the foot as either grade 3(O) (if <2 SIRS criteria) or grade 4(O) if ≥2 SIRS criteria) (see for further details the IWGDF Infection Guideline (7); please be aware that the addition of (O) has not yet been validated in prospective studies)

REFERENCES

(1) IWGDF Editorial Board. IWGDF Definitions and Criteria. 2019; Available at: <u>https://iwgdfguidelines.org/definitions-criteria/</u>. Accessed 04/23, 2019.

(2) Jeffcoate WJ, Bus SA, Game FL, Hinchliffe RJ, Price PE, Schaper NC, et al. Reporting standards of studies and papers on the prevention and management of foot ulcers in diabetes: required details and markers of good quality. Lancet Diabetes Endocrinol 2016 Sep;4(9):781-788.

(3) Schaper NC, Van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ, Lipsky BA. IWGDF Practical Guidelines on the prevention and management of diabetic foot disease. Diabetes Metab Res Rev 2019;in press.

(4) Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco ICN, et al. IWGDF Guideline on the prevention of foot ulcers in persons with diabetes. Diabetes Metab Res Rev 2019;in press.

(5) Bus SA, Armstrong DG, Gooday C, Jarl G, Caravaggi CF, Viswanathan V, et al. IWGDF Guideline on offloading foot ulcers in persons with diabetes Diabetes Metab Res Rev 2019; in press.

(6) Hinchliffe RJ, Forsythe RO, Apelqvist J, Boyko EJ, Fitridge R, Hong JP, et al. IWGDF Guideline on the diagnosis, prognosis and management of peripheral artery disease in patients with a foot ulcer and diabetes. Diabetes Metab Res Rev 2019;in press.

(7) Lipsky BA, Senneville E, Abbas ZG, Aragón-Sánchez J, Diggle M, Embil J, et al. IWGDF Guideline on the diagnosis and treatment of foot infection in persons with diabetes. Diabetes Metab Res Rev 2019;in press.

(8) Rayman G, Vas PR, Dhatariya K, Driver VR, Hartemann A, Londahl M, et al. IWGDF Guideline on interventions to enhance healing of foot ulcers in persons with diabetes. Diabetes Metab Res Rev 2019;in press.

(9) Monteiro-Soares M, Russell D, Boyko EJ, Jeffcoate WJ, Mills JL, Morbach S, et al. IWGDF Guideline on the classification of diabetic foot ulcers. Diabetes Metab Res Rev 2019;in press.

(10) Moore Z, Butcher G, Corbett LQ, McGuiness W, Snyder RJ, van Acker K. Exploring the concept of a team approach to wound care: Managing wounds as a team. J Wound Care 2014 May;23 Suppl 5b:S1-S38.